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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

METZMAIER, DANIEL S

ART UNIT

PAPER NUMBER

1712

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 10/045,835	Applicant(s) LIST ET AL.	
	Examiner Daniel S. Metzmaier	Art Unit 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-61 are pending in the instant application. The Office Letter Regarding the Declaration mailed 8 February 2002 has been entered as Paper No. 2. Applicants' Letter (request for refund) filed 4 March 2002 has been entered as Paper No. 3. The corrected Declaration filed 12 March 2002 has been entered as Paper No. 4.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 11 January 2001. It is noted, however, that applicant has not filed a certified copy of the German application, DE 101 00 867.8, as required by 35 U.S.C. 119(b).

Drawings

2. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

3. The disclosure is objected to because of the following informalities: the item in the figure¹ denoted "3" does not have a corresponding description in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

¹ It is noted the numbering, 1-6 of the sole figure, does not include "4". There is no objection to the numbering in the drawing but is pointed out for applicants convenience.

5. Claims 1-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing and/or misleading. Claims 1-34 are directed to methods of generating an aerosol. The first step of the method is to "guiding a gas having input particles suspended therein". A gas suspension of input particles is an aerosol. It is unclear where is the aerosol generating step since the process starts with an aerosol.

In claim 7, it is unclear what is the scope of "feeding" the input particles into the gas at rest since said step would define aerosol generating which is not further set forth.

In claim 26, it is unclear whether applicants intend just the carrier or the carrier and the agent. The agent is not positively recited.

In claim 29, the term solvent is indefinite because it is unclear what the solvent solvates.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 7, 9-11, 13-24, 26-29, 34-36, 39, 41-44 and 46-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al., 4,972,830. Wong et al (figures and columns 3-8; particularly columns 7 and 8) disclose an inhalation device and methods of using said device. Wong et al (column 8, lines 5-9) discloses upstream

pressures of 50 psig. 50 psig equates to about 3.4×10^5 Pa. Wong et al (column 8, lines 10 et seq) characterizes the function of the disclosed inhaler, wherein the gas stream is supersonic in the inlet restriction 86. Wong et al characterizes the stream flows without further significant change in volume or velocity until it reaches aperture 84 wherein upon expansion into chamber 20 undergoes shockwave. See Wong et al (figure 5) elements 96 and 92 and 94 for claims 3 and 36.

Wong et al (column 7, lines 51-53, 58, 66; and column 9, lines 11 et seq) discloses the incorporation of a medicament, solvent and the breaking of the particles into smaller particles.

The inhaler device is intended to be used at ambient room temperature. The temperature of the gas would have been inherent to the use of the Wong et al device. Inert gases such as N_2 are conventionally used for inhalers. Claim 17 is deemed inherent to the use of the Wong et al device.

Wong et al (column 8, lines 48) teaches the inhaler device forms a aerosolized mist having particle sizes of 1 to 3 microns and reads on applicants' preferred range. Wong et al (column 9) discloses the particles are broken up by the device. Since the resulting aerosol particle size is the same and the process is otherwise the same, the use of input particles having much larger particle sizes in the range of 10 to 100 times larger would have been inherent to those employed in the Wong et al process.

Solvents as used in Wong et al is indistinct from applicants claimed liquid carrier set forth in claim 26.

It is noted applicants' claims employ transitional language comprising, which does not exclude further steps and/or elements of the methods and device. Furthermore, the direction of flow has not been defined other than relative features of the device and or the direction of flow from higher pressure to lower pressure. Therefore, the path of flow reads on geometric paths other than linear. Claims 39-44 do not exclude the supply devices which supply both the gas and input particles from the same device. the use of an aerosol spray reads on storage tank.

The claimed feeding of the particles to the gas at subsonic velocity is implicit to feeding the medicament to the gas upon filling of the inhaler (see instant claim 7). Rest is subsonic velocity.

Claim 49 is included in the rejection as inherent since the reference contemplates pressures of up to 50 psi ($3.4 \cdot 10^5$ Pa). A prudent engineer would employ a vessel capable of withstanding pressures well in excess of the gas pressures employed, i.e., substantially $5 \cdot 10^5$ Pa, to advantageously remove the risk of explosion and to be safe.

8. Claims 1, 6, 8-11, 13-24, 34, 39-40, 43-44 and 46-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Boiarski et al., 4,268,460. Boiarski et al (figures; column 1, lines 24 et seq; column 6, lines 59 et seq; column 7, lines 33 et seq) discloses a nebulizer wherein the particles are reduced in size by being accelerated to supersonic velocity followed by a shock wave resulting from the supersonic to subsonic transition.

Since the apparatus has application in the treatment of lung therapy, the temperature would be expected to be about room temperature for breathability by the

user. The limitations of claims 13-16 are deemed inherent to the use of the Boiarski et al apparatus.

For the limitations of claims 18-23 and 55-60, please see figure 4-8.

Claim 49 is included in the rejection as inherent since the reference contemplates pressures of up to 60 psi ($4.1 \cdot 10^5$ Pa). A prudent engineer would employ a vessel capable of withstanding pressures well in excess of the gas pressures employed, i.e., $5 \cdot 10^5$ Pa, to advantageously remove the risk of explosion and to be safe.

9. Claims 1-4, 9, 13, 17, 24, 31-32, 34-46, 50, 54 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner, US 4,294,208. See figure 2 and columns 2-4. The temperature range claimed is broad enough to encompass the fuel-air mix (column 2, line 50).

10. Von Rosenberg, Jr. et al, US 4,278,446, is considered cumulative for at least claims having a DeLaval nozzle, semi-solid or solid particles and water as a carrier. Please note designation 26 in the figure which corresponds to shock waves. Designation 20 is a pump. Coal and/or char are both fed into a gas stream.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 13-16, 18-20, 50-53 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al., 4,972,830. Wong et al discloses inhaler devices and methods of using said inhaler devices in the above rejection, which is incorporated herein by reference.

To the extent Wong et al differs from the claims in the temperature of the gas or the particle size of the input particles, said parameters are dependent on the particular composition and medicament employed and/or the amount of agitation acted on the gas input particles prior to discharging the inhaler composition from the pressurized container.

It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to agitate and vary the input particles size in the gas prior to discharge for the advantage of a more finely dispersed aerosol. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to vary the temperature of the gas at rest as a result of normal use in varied ambient temperatures.

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14. Claims 24-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al., 4,972,830, as applied to claims 1-4, 7, 9-11, 13-24, 26-29, 34-36, 39, 41-44 and 46-61, above, and further in view of Sallmann et al, 5,096,917, or Gleason et al, 4,552,893. Wong et al discloses methods and apparatus for aerosolizing materials as set forth in the above anticipation and obviousness rejections by/over the same.

Said characterizations have been incorporated herein by reference.

Wong et al differs from the claims in the use of water, alcohol, a semi-solid, solid active ingredients.

Sallmann et al (column 9, lines 48 et seq ; column 10, lines 22 et seq ; and example A) discloses aerosol compositions wherein the compositions may be dispensed by a metered dose apparatus. Sallmann et al (column 10, lines 22 et seq) teaches the use of micronized particles having advantageously less than 5 micron particle sizes; solutions, suspensions and emulsions as carriers; and pharmaceutical excipients including water and ethanol as conventional.

Gleason et al (column 5, lines 58 et seq, and column 6, lines 17 et seq) discloses pharmaceutical compositions may be in a carrier such as a solution or suspension of water or alcohol among others. Gleason et al teaches the compositions may be dispensed by a pressurized aerosol.

These references are combinable because they teach aerosol compositions and aerosol apparatus for dispensing said compositions. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ the conventions compositions employing a solution or suspension in a water based carrier

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or an alcohol based carrier taught to be conventional in the Sallmann et al or Gleason et al references in the apparatus and methods of the Wong et al reference. Furthermore, it would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ a micronized powder taught in the Sallmann et al reference in the apparatus and methods of the Wong et al reference.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al., 4,972,830, as applied to claims 1-4, 7, 9-11, 13-24, 26-29, 34-36, 39, 41-44 and 46-61, above, and further in view of Sanders, "Principles of Aerosol Technology", pages 18-33. Wong et al discloses methods and apparatus for aerosolizing materials as set forth in the above anticipation and obviousness rejections by/over the same. Said characterizations have been incorporated herein by reference.

Wong et al differs from the claims in the use of a gas at a pressure of substantially $5 \cdot 10^5$ Pa.

Wong et al (column 7, lines 61-63) teaches the pressure of the gas may be dependent on the container employed and (column 8, lines 4-5) that the ratio of the gas pressure to the ambient pressures be greater than the critical pressure ratio.

Sanders teach a number of propellants including Freon 12 that has a pressure that is substantially $5 \cdot 10^5$ Pa.

16. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner, US 4,294,208, as applied to claims 1-4, 9, 13, 17, 24, 31-32, 34-46 50, 54 and 61, above, and further in view of Pool, US 2,873,756.

Wagner discloses methods and apparatus for aerosolizing materials as set forth in the above anticipation rejection by the same. Said characterizations have been incorporated herein by reference.

Wagner differs from claim 5 in the point of the shock wave.

Pool teaches (column 1, lines 18-33) by small pressure variations, the point in the nozzle of the shock wave may be moved.

These references are combinable because they teach Laval nozzles and their properties. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention to vary the point of the shock wave for the optimal burn of the fuels as clearly desired in the Wagner reference.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boiarski et al., 4,268,460 is considered cumulative to Wong et al., 4,972,830, as applied in view of Sallmann et al, 5,096,917, or Gleason et al, 4,552,893. Newhouse et al, US 5,349,947, is considered particularly relevant to some of the claimed embodiments. See at least column 10, line 38, to column 11, line 10.

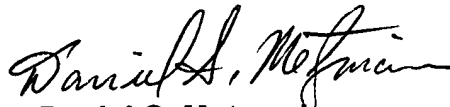
Also, see Piper, US 6,338,443, is considered particularly relevant. See column 6, lines 12-36.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (703) 308-0451. The examiner can normally be reached on 9:00 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson can be reached on (703) 308-2340. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Daniel S. Metzmaier
Primary Examiner
Art Unit 1712

DSM
January 15, 2003